



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

Re: Androderm®  
Docket No. 95E-0420

FEB 22 1996

Stephen G. Kunin  
Deputy Assistant Commissioner for  
• Patent Policy and Projects  
Office of the Assistant Commissioner for Patents  
U.S. Patent and Trademark Office  
Crystal Park Building 2, Suite 919  
Washington, D.C. 20231

#13

Dear Mr. Kunin:

This is in regard to the application for patent term extension for U.S. Patent No. 4,983,395 filed by TheraTech Inc. under 35 U.S.C. § 156. The human drug product claimed by the patent is Androderm® (testosterone), which was assigned New Drug Application (NDA) No. 20-489.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). Our records also indicate that it **does not** represent the first permitted commercial marketing or use of the product. The attached list includes products that have been previously approved and contain the same active ingredient, testosterone, as in Androderm®.

The NDA was approved on September 29, 1995, which makes the submission of the patent term extension application on November 24, 1995, timely within the meaning of 35 U.S.C. § 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the Federal Register, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely,

Ronald L. Wilson, Director  
Health Assessment Policy Staff  
Office of Health Affairs

cc: Antoinette F. Konski  
Morrison & Foerster  
755 Page Mill Road  
Palo Alto, CA 94304

**Previously Approved Products Containing the Active Ingredient  
Testosterone\***

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ORETON-F OINTMENT  
PERANDRENAL OINTMENT  
MALE SEX HORMONE INJECTION  
TESTRYL INJECTION  
TRIPLE HORMONE SUSPENSION/INJECTION  
MYOSOL TESTOSTERONE  
TESTODERM TESTOSTERONE TRANSDERMAL SYSTEM  
TESTOSTERONE

\* This list was compiled on January 24, 1996.